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Patient-Specific 3-Dimensional-Printed Orthopedic Implants and Surgical Devices Are Potential Alternatives to Conventional Technology But Require Additional Characterization

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Background: Three-dimensional (3D) printing allows anatomical models, guides, and implants to be easily customized to individual patients. Three-dimensional–printed devices can be used for a number of purposes in the medical field, yet there is a lack of data on the implementation of 3D-printed patient-specific implants and surgical guides in orthopedics. The objective of this review of the literature was to summarize the implementation of 3D printing in orthopedic surgery and identify areas that require more investigation.

Methods: PubMed and Scopus were used to perform a literature search. Articles that described 3D-printed patient-specific orthopedic implants or intraoperative guides were reviewed. Relevant articles were compiled and summarized to determine the role of personalized 3D-printed implants in orthopedic surgery.

Results: A total of 58 papers were selected. Overall, 3D-printed implants and surgical guides were shown to be effective in the selected cases. Patients with bone tumors benefitted from custom 3D-printed implants, which allow aggressive resection while preserving the function and mechanical stability of the limb. Eighty-one percent of devices were made using titanium, and 48% of articles reported the use of 3D printing in oncology. Some reported adverse events including wound dehiscence, periprosthetic infection, dislocation, and sequelae of malignancy. Regulations surrounding the use of 3D-printed surgical devices are ambiguous.

Conclusions: Three-dimensional–printed orthopedic implants and guides present an alternative to commercial devices, as they allow for customizability that is useful in cases of anatomic complexity. A variety of materials were surveyed across multiple subspecialties. Large controlled studies are necessary to compare patient-specific implants with the standard of care and evaluate their safety profiles over time.

Keywords: *Tumor, Bone fractures, Orthopedic surgery, Three-dimensional printing, Patient-specific*

The frequency of orthopedic surgeries is incredibly high in United States hospitals, with musculoskeletal procedures ranking as the most common inpatient operating room procedure in 2012.[1] The growing quantity of orthopedic procedures fuels innovation that can aid in the efficiency, success, and safety of these surgeries. Many orthopedic surgeries require replacement or repair of bone tissue, and therefore the need for orthopedic implants is rapidly increasing.[2] Implants can be manufactured from a number of materials with Bioproperties that facilitate implantation. These include titanium, stainless steel, tantalum, polyethylene, and ceramics.[3]

Implant technology has been increasingly improving

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over the past years, with a special focus on patient-specific implants. Patient-specific implants are engineered to fit the individual's unique anatomy, therefore constituting an effective treatment for many different clinical conditions. Ultimately, the goal is to use these implants to reduce overall procedure costs, minimize surgical time, and maximize patient outcomes.[4]

One method of manufacturing patient-specific implants is three-dimensional (3D) printing technology. Three-dimensional printing is an additive manufacturing process whereby a selected material is laid down layer by layer based on a computer-aided design (CAD) model of the desired shape.[5] In orthopedics, 3D printing is used for a number of purposes, including both patient-specific implants and surgical guides. Other uses have been reported for personalized presurgical treatment, preoperative planning, customized surgical tools and prostheses, testing medical devices, aiding in medical training and patient education, bioprinting, and customizing synthetic organs.[6] Three-dimensional printing is especially exciting for intraoperative use in orthopedic procedures. Compared to traditional production, 3D printing can be implemented on demand on-site, without the need for a centralized manufacturing location.[7] Overall, patient-specific 3D-printed implants and guides provide new technology for increased precision and productivity in treating complex musculoskeletal pathologies.

Despite the promising advantages of 3D printing, it is still a developing method and thus requires comprehensive review. Regarding intraoperative implants and guides, these materials contact the patient directly, meaning there are more factors to consider in their design. While isolated cases have demonstrated the efficacy of 3D-printed implants and guides in orthopedic surgery, there lack sufficient high-quality studies that investigate the safety and efficacy of this new technology. Therefore, it is challenging for physicians to decide how to implement 3D printing in practice. This literature review consolidates relevant published cases to summarize recent applications of the technology in orthopedics.

METHODS

The literature review was performed using Scopus and PubMed, with the following search terms: "(3D printing) AND (orthopedic surgery) AND (personalized OR custom)". Searches were not limited by the date of publication, although all selected articles were published in 2015 or later. A narrative review of the literature was conducted up to April 2023 by 2 authors (APM and TM). Table 1 outlines the selected articles.[8-65]

The inclusion criteria included articles in English describing patient-described 3D-printed materials that were used intraoperatively as an implant or surgical guide for orthopedic indication. The exclusion criteria included non-English articles, review articles, and articles focused on preoperative planning, preclinical development, or physical characterization of materials.

RESULTS

A total of 58 papers were selected for analysis in this review of the literature (Table 1). The articles presented various uses of 3D-printed implants and surgical guides in the field of orthopedic surgery.

A Variety of Materials Are Being Used to Fabricate 3D-Printed Implants and Guides

There are a few techniques that are used more often in orthopedic surgery applications. The literature review revealed that most CAD models of orthopedic implants and surgical guides are derived from patient CT scans with a small slice thickness (typically 1–2 mm).[12] Metal is typically used to provide a high level of strength for the bone implants.

Fig. 1 shows the distribution of materials being used for implants within the selected articles. Of the 47 articles that use implants, titanium alloy is the most common material (81% of articles). This is prepared using electron beam melting or selective laser melting of a titanium alloy. Ti_6Al_4V in particular has been extensively characterized, and its porous form has "excellent biocompatibility, superior corrosion resistance, durability, osseointegration capability, relatively low elastic modulus, and high strength-to-weight ratio."[44] Multiple studies demonstrate beneficial properties of the material in the orthopedic setting. For example, Girolami et al.[25] developed and utilized Ti_6Al_4V implants with an inner lattice structure that mimics cancellous bone and a dense outer shell to mimic the properties of cortical bone. In another study by Wong et al.,[62] the mechanical properties of the implant are tailored to the patient's specific anatomy for the treatment of pelvic chondrosarcoma. The porosity of the prosthesis was set at 70% to allow bone ingrowth, and the elastic modulus of the implant was comparable to that of bone to minimize the risk of stress shielding.

Fig. 2 shows the distribution of guide materials among the 17 articles that used surgical guides. Other than articles that did not specify the material, poly-lactic acid (PLA) is most commonly used (29% of articles). Other

Table 1. Selected Articles Listed by Authors, Year, Number of Patients, Country of Study, Methods (Including Indication and Surgical Approach), and Major Findings (Including Function, Radiology, Adverse Events, etc.)

Study	No. of patients	Country	Method	Major finding
Alessandri et al. (2022)[8]	1	Italy	Three-dimensional–printed patient-specific PLA cutting plate to guide osteotomies and customized structural wedge allograft as a treatment for severe bilateral genu varum	The planned surgery was accurately replicated at the time of operation. However, the 1-year follow-up revealed a slight recurrence of varus deformity. No significant deformation or mechanical problems of the cutting guides were observed.
Amelot et al. (2018)[9]	6	France	Polyether ketone vertebral body replacement for cervical spondylotic myelopathy	Angle measurements (C2–C7 Cobb and corpectomy Cobb angles) remained constant during 21-month follow-up period; no hyperlordosis or kyphosis detected; no height differences between preoperative and follow-up dates; improved Neck Dysfunction Index scores; VAS scores improved; all patients developed fusion. One patient developed a subclinical adjacent lower vertebrate end plate impaction.
Angelini et al. (2019)[10]	13	Italy	Prospective analysis of patients with primary bone tumor, bone metastasis, or total hip arthroplasty revision, who were treated with resection and a custom titanium prosthesis	All patients were alive at mean follow-up of 13.7 months. Mean MSTS score was 80.3% at last follow-up.
Angelini et al. (2020)[11]	41	Italy	Retrospective analysis of procedures with custom 3D-printed titanium prosthetics to reconstruct bone defect after resection of a bone tumor or a revision surgery	At 5-year follow-up, overall survival in the oncologic group was 89% by Kaplan-Meier curves of survival. Mean MSTS score at follow-up was 73%. Three patients died of disease, 1 patient required implant removal due to deep infection, and 4 had local recurrence. Overall complication rate was 22%.
Ao et al. (2022)[12]	6	China	Total knee arthroplasty revision (due to aseptic loosening, prosthetic joint infection, or instability) using porous tantalum cones	Increased function indicated by higher Hospital for HSS scores, decreased VAS scores indicating decreased pain compared with preoperative scores; radiological evidence of implant stability; bone defects effectively reconstructed.
Beltrami et al. (2021)[13]	1	Italy	Titanium alloy implant and autograft for reconstruction of osteosarcoma of the humerus	Free from local and distant disease progression at 3-year follow-up; hand and wrist show complete functionality; complete recovery of sensory function; MSTS score for upper limb is 26/30 at 3-year follow-up. No major complications, slight limitation of activity; superficial dehiscence in early postoperative period
Beltrami et al. (2018)[14]	1	Italy	First phalangeal giant cell tumor resection and prosthetic reconstruction using titanium alloy	ROM in metacarpophalangeal joint maintained; disease-free at 2-year follow-up with good MSTS score ROM in proximal interphalangeal joint limited to 80° flexion at 1 year postoperatively
Brandsma et al. (2021)[15]	1	Netherlands	Customized Ti_4Al_6V 3D-printed proximal ulna used in hemiarthroplasty following resection of ulnar chondrosarcoma	Radiographs showed adequate positioning of the prosthesis with no loosening or wear. Active extension of the elbow was limited at 10°, with a Disabilities of Arm, Shoulder and Hand questionnaire score of 25.8 points. CT scan showed good ingrowth into the ulna, and no signs of osteoarthritis in the distal humerus. A developing lucent zone was seen at the distal anterior zone of the ulnar stem. Slight sensitivity loss in the fifth digit appeared immediately postoperatively and persisted.
Caravelli et al. (2022)[16]	4	Italy	Trabecular titanium metal spacer for treatment of tibial pilon septic nonunion	AOFAS and VAS scores showed functional improvement for all patients at last follow-up; radiologic signs of osseointegration between 4–6 months for all patients No major complications; 1 wound healing delay, nail removal in 1 patient due to intolerance

Table 1. Continued

Study	No. of patients	Country	Method	Major finding
Chen et al. (2021)[17]	1	China	Limb salvage procedure for distal radius osteosarcoma using porous tantalum implant and PLA surgical guide	Complete pain relief and satisfactory extension at 2-year follow-up Limited flexion of the wrist remains.
Chen et al. (2021)[18]	1	China	Subtotal removal and reconstruction of chronic clavicle osteomyelitis	Complete pain relief and satisfaction with shoulder appearance and function; reduced operation time and blood loss due to lack of graft harvest from lower limb; no failure or loosening of implant
Cheng et al. (2022)[19]	7	China	Resin-based 3D-printed surgical guide plates to assist with Schanz screw insertion in order to install the monorail external fixator in surgical treatment of leg length discrepancy	The usage of guide plates increased the precision of Schanz screw positioning, reducing the risk of articular rupture and fixation failure. Lower extremity function score had a statistically significant increase from 32.17 ± 8.57 to 61.17 ± 6.68 after surgery. Two patients were readmitted to the hospital with infection at 1 week and 1 month and were treated appropriately.
Dong et al. (2022)[20]	17	Switzerland	Resection of pelvic and extremity bone tumor-limb salvage surgery using custom osteotomy guide	Sixty-three of 64 osteotomies achieved wide resection and negative margins confirmed by pathology reports; 73.3% 5-year survival rate; no local recurrence Swing of sawing in 1 case contaminated tumor tissue, no recurrence or metastasis until after adjuvant radiation therapy
Duan et al. (2019)[21]	29	China	Subtalar joint arthrodesis using customized PLA guides for drilling of Kirschner wires	Decreased time to drill Kirschner wires into correct position, fewer cases of re-drilling, radiographic fusion confirmed in all cases; no difference in fusion time and AOFAS scores between experimental and control groups No serious perioperative complications
Fidanza et al. (2022)[22]	1	Italy	Three-dimensional–printed custom-made Ti_4Al_6V implant for revision surgery after infection and massive bone loss following total hip arthroplasty	At 6-month follow-up, the implant was well positioned and the radiograph demonstrated osseointegration. There was no infection or pain and the patient returned to normal activities of daily living.
Gemalmaz et al. (2017)[23]	1	Turkey	Custom 3D-printed resection guide to assist in intercalary grafting osteotomy to correct cubitus varus deformity	Postoperative x-ray showed perfect conformity of the plate and screw fixation, matching the preoperative plans. At week 4, there was no pain around the joint and no lateral condylar prominence. Three-month follow-up showed full ROM without pain and confirmation of osteotomy site union.
Girolami et al. (2022)[24]	2	Italy	Ti_4Al_6V prosthesis for upper cervical reconstruction following extracapsular debulking of C2 chordoma	Radiographic evidence of stability and gross evidence of osseointegration on subsequent procedure for disease recurrence No perioperative complications during implantation, patients died from either sequelae of the malignancy or surgical complication of secondary resection.
Girolami et al. (2018)[25]	13	Italy	Ti_4Al_6V reconstruction of anterior spinal column reconstruction in the thoracolumbar spine post-*en bloc* resection of both primary and metastatic spinal tumors	Minor subsidence into adjacent vertebral bodies, immediate stability of implant and no cases required intraoperative change in reconstruction technique. No prostheses broke, and no migration occurred; 1 prosthesis removed due to discovery of new disease on distal end.
Grossi et al. (2020)[26]	4	Italy	Three-dimensional–printed Ti_4Al_6V prosthesis for partial and total scapular reconstruction following *en bloc* scapulectomy	At 2-year follow-up, patients with partial scapulectomy had an MSTS of 76% and good clinical results with no pain. At 1.5-year follow-up, patients with full scapulectomy had an MSTS of 46% and fair clinical results with no pain.

Table 1. Continued

Study	No. of patients	Country	Method	Major finding
Hao et al. (2021)[27]	12	China	Patient-specific Ti_4Al_6V prostheses for total hip arthroplasty revision surgery	Prosthetic position highly corresponded with preoperative location planning. Harris scores were significantly improved after revision, and no patients underwent re-revision surgery. There was 1 case of postoperative periprosthetic infection and 1 case with hip dislocation.
Hou et al. (2022)[28]	1	China	Debridement and reconstruction of ipsilateral femur and tibia defect using custom Ti_4Al_6V prosthesis	Satisfactory clinical result and radiographic evidence of osseointegration at 26-month follow-up; no implant loosening or breakage detected
Hou et al. (2020)[29]	5	China	Reconstruction of metaphyseal segmental femur defect using custom titanium implants	Radiographic evidence of osseointegration; Harris hip score excellent in 2 cases, god in 2 cases, fair in 1 case; HSS score of knee joint good in 4 cases, middle in 1 case No implant loosening, subsidence, infection, or loss of correction
Hu et al. (2022)[30]	16	China	Periacetabular tumor wide resection and pelvic reconstruction with a 3D-printed Ti_4Al_6V hemipelvic endoprosthesis	After at least 6 months, CT showed prosthetic porous structure-bone fusion. At last follow-up 12 patients lived without disease, 15 had independent ambulation, and no patients experienced pain. Mean MSTS was 85.8%. Two patients experienced DVT, 2 patients had pneumonia, and 2 had infection. Two patients had dislocated hips at follow-up and were treated with revision surgery.
Hu et al. (2019)[31]	7	China	Three-dimensional–printed nylon guiding baseplate for implantation of 3D-printed Ti_4Al_6V glenoid prosthesis in reversible shoulder arthroplasty following en-bloc resection of proximal humerus tumor	At final follow-up, mean MSTS was 85.7% and mean Toronto Extremity Salvage Score was 90.0%. No instability, infection, loosening, or fracture One patient with giant cell tumor experienced pulmonary metastasis, and 1 patient with osteosarcoma died of pulmonary metastasis.
Huang et al. (2015)[32]	6	China	Internal fixation of tibial plateau fracture using personalized acrylate resin guide	No significant differences found between preoperative and postoperative screw trajectories, screw lengths, entry points, and screw directions. No major complications reported.
Imanishi et al. (2015)[33]	1	Australia	Case study of a total calcanectomy followed by implantation of a calcaneal prosthesis	A custom calcaneal implant allowed the patient to be free of pain at 5-month follow-up and walking unsupported on bare feet. ROM restricted but ankle stable anterior-posteriorly and laterally. AOFAS score was 82.
Ji et al. (2020)[34]	80	China	*En bloc* resection of pelvic tumor followed by reconstruction with endoprosthesis	No acetabular component instability was detected on radiographic evaluation after a mean duration of 32.5-month follow-up. At last follow-up, 59 patients were alive with disease. Mean MSTS was 83.9%. One SI joint screw break reported. Complications in 16 patients, with wound dehiscence the most common (8 patients). At last follow-up, 16 patients died of disease and local recurrence in 9 patients.
Jovicic et al. (2021)[35]	11	Croatia	Retrospective review of pelvic and humeral bone tumor resections followed by reconstruction with custom implants	Custom implants allowed remission in many cases; good functional recovery and cosmetics Four patients died of disease, 3 patients had implant dislocation, 1 case of leg-compartment syndrome, 1 patient reported limited ROM; only 2 of 11 patients developed local recurrence.
Li et al. (2022)[36]	7	China	Hemiarthroplasty following tumor resection of the distal femur using 3D-printed PA2200 uncemented unipolar prosthesis	As of the last follow-up, 6 patients survived without metastasis or local recurrence. One patient died of metastasis at 19 months postoperatively. Elongation of the tibia was seen in all cases and the mean MSTS score was 25.8. Painless joint space narrowing was observed in 2 patients. In 1 patient, the screw for ligament fixation loosened at 17 months postoperatively.

Table 1. Continued

Study	No. of patients	Country	Method	Major finding
Liang et al. (2017)[37]	35	China	*En bloc* resection of a pelvic tumor followed by implant of customized endoprosthesis	At mean follow-up of 20.5 months, 25 patients survived without evidence of disease. Mean MSTS was 19.1. Fusion was seen between graft and sacrum for 18 patients whose operation included a femoral head autograph. At last follow-up, 5 patients died of metastatic disease. Seven patients with delayed wound healing and 2 with dislocation of the hip. No infection
Ma et al. (2017)[38]	12	China	Customized Ti_4Al_6V plate implants for reconstruction assistance following microwave-induced hyperthermia to treat bone tumor	Mean MSTS score was 27.17 and the mean value of maximum flexion of the knees was 114.08°. Knee gait analysis was comparable with normal population data. No postoperative fractures, implant failures, or loosening problems occurred. One patient had a superficial infection, treated with debridement and antibiotics. One patient had a peroneal nerve injury. One patient had local recurrence and died 14 months later of lung metastases.
Ma et al. (2016)[39]	8	China	Three-dimensional–printed Ti_4Al_6V guide templates to assist in resection of tumorous bone and insertion of bone implants in treating osteosarcoma	The use of the guide template led to more precise resection of the tumorous bone and insertion of the implants, less blood loss, shorter operation time, and reduced radiation exposure. Upon final follow-up, patients had a mean MSTS score of 27.125. At 2 years, patients were alive and well without recurrence.
Marinelli et al. (2022)[40]	2	Italy	Two patients with triplanar cubitus deformity, treated with step-cut corrective osteotomies used customized 3D-printed photopolymer resin guides	Radiographs demonstrated bone consolidation at 3-month follow-up for both patients. No pain, no neurological disturbances, and a good aesthetic. No hardware problems or other complications were observed.
Mobbs et al. (2017)[41]	2	Australia	Resection and reconstruction for C1/C2 chordoma using titanium fusion cage	Implants easily inserted into position, allowing shortened operation time; radiological evidence of successful fusion at 9 and 12 months; no failure of fixation and no subsidence; visual analog score improvements Temporomandibular joint dysfunction secondary to prolonged stretching of oral cavity and upper esophageal stricture
Oraa et al. (2021)[42]	6	Spain	Customized Ti_4Al_6V surgical guides for femoral osteotomies with rotational malalignment after a traumatic diaphyseal fracture	All patients presented with a normalized anteversion angle of the femur, according to their contralateral limb. Using 3D-printed guides made the surgery shorter and technically easier and decreased the amount of radiation inside the operating room.
Ozturk et al. (2020)[43]	20	Turkey	Customized 3D template to guide screw and plate placement in treatment of tibial plateau fractures	Customized 3D model provided a radiation-free tibial screw insertion. Duration of operation, blood loss volume, tourniquet time, and number of intraoperative fluoroscopy decreased in the 3D printing group.
Park et al. (2018)[44]	1	Korea	Limb salvage surgery for calcaneal desmoplastic fibroma using Ti_4Al_6V implant	Full weight-bearing at 12 weeks; able to walk without limping or supports at 16 months No adverse events postoperatively; no complications at 16-month follow-up; mild discomfort at plantar side of heel when patient started to walk, but diminished after initial steps.
Park et al. (2018)[45]	12	Korea	Limb salvage surgery using patient-specific 3D-printed bone tumor resection guide	Resection margin statuses were histologically negative for all patients. The mean cutting error for the shortest margin was 1.2 mm, and for the greatest margin was 1.4 mm. The maximal cutting error was 3 mm. One patient experienced local recurrence.
Park et al. (2021)[46]	12	Korea	Pelvic tumor resection and reconstruction with patient-specific implant	Independent gait recovered in all patients but 1. Average emotional MSTS score was 4.8. One patient underwent hind-quarter amputation at 4 months postoperatively due to recurrence.

Table 1. Continued

Study	No. of patients	Country	Method	Major finding
Park et al. (2021)[47]	2	Korea	Revision limb salvage surgery with patient-specific implant	Revision surgeries were performed to preserve the previous implants as much as possible. At 30 months, MSTS was 26 for the patients with ulnar surgery, and MSTS was 30 for the patients with femur surgery.
Park et al. (2021)[48]	1	Korea	Analysis of a delayed fracture that occurred 6 months after the replacement of cancer-resected bone with a 3D-printed implant	Microstructural aspects and implant design contributed to the fracture. Tiny gas pores were observed in the implant material, and cracks originated at clusters of unmelted powder. Mesh Ti_6Al_4V had poor elongation characteristics, which were not able to withstand the physiological load of walking, especially where the mesh connected with the solid area of the implant.
Putzier et al. (2017)[49]	4	Germany	Three-dimensional–printed polyamide template for pedicle screw insertion in correction of severe scoliosis	Overall, 76 pedicle screws were implanted and 2 were misplaced and thus repositioned. CT scans showed no medial pedicle violation, and no misplaced screw contact to neurovascular structures. On the 4-tiered classification system, 84% of screws were graded 0. Clinical results and correction of deformities were excellent in all patients, with a mean correction of 91%.
Savov et al. (2021)[50]	10	Germany	Customized 3D-printed Ti_4Al_6V revision total knee arthroplasty implants	Mean passive postoperative ROM was 92°. No fractures were observed intra- or postoperatively. Mean preoperative VAS scale was 8.1 points, and mean postoperative VAS scale was 2 points. Six patients had an infection and 2 had an aseptic loosening. Two patients were revised post-surgery due to persistent hematoma, and persistent infection.
So et al. (2018)[51]	3	United States	Custom 3D-printed titanium truss implant to treat large osseous defects	All patients ambulating without pain at 12 weeks and 12-month follow-up CT showed > 50% osseointegration of the implant to the surrounding cortical and cancellous bone. One patient had previously undergone total ankle replacement and the skin was compromised. They developed a postoperative infection that was treated with local wound care and antibiotics.
Tetsworth et al. (2019)[52]	5	Australia	Patient-specific Ti_4Al_6V cages in conjunction with the Masquelet technique to reconstruct posttraumatic segmental femoral defects	All patients achieved union via clinical and radiographic measures. Histology and immunohistochemistry indicated a greater number of vessels, cell nuclei, PECAM-1, CD68, and VEGF in induced membranes compared to the local fascia controls. At last follow-up, all patients were ambulating, full weight-bearing, and pain free. There were no deep infection, fractures, nerve injuries, loss of alignment, or nonunions identified in the 21-month follow-up. One patient had limited knee ROM, there was 1 superficial stitch abscess, and 1 patient had several locked screws disengaged from a plate. All complications were resolved.
Tredan et al. (2022)[53]	1	Switzerland	Spinal revision surgery using patient-specific Ti_4Al_6V implant to correct failed cervical disc replacement	Postoperative CT revealed a well-seated implant and an improvement in the sagittal balance. Patient was asymptomatic and pain free at 3-month follow-up. Repeat CT showed continued appropriate placement of the implant and early osseointegration.
Tu et al. (2019)[54]	9	China	Patient-specific 3D-printed guide templates for pedicle screw placement in asymmetric wedge pedicle subtraction osteotomy for treatment of severe kyphoscoliosis resulting from ankylosing spondylitis	At final follow-up, all patients had bone fusion at the osteotomy site without screw loosening, as shown by CT. Two patients experienced hypoesthesia of the lower limbs; resolved at the last follow-up.

Table 1. Continued

Study	No. of patients	Country	Method	Major finding
Verma et al. (2021)[55]	1	India	Osteochondroplasty using customized 3D-printed polylactic acid customized head and neck jigs as treatment for Cam type femoroacetabular impingement	At 1-year follow-up, the patient was pain free and with a fair ROM. Jigs aided during surgery by ensuring resection of the correct amount of bone.
Vitiello et al. (2022)[56]	14	Italy	Limb salvage and bone tumor resection using Ti_4Al_6V prostheses	All patients except 1 reported excellent satisfaction with treatment; no significant changes in Karnofsky performance status scores No intraoperative complications; early postoperative complications were limited and included urinary infection and wound dehiscence; only 1 patient died 11 months postoperatively due to oncologic disease.
Voloshin et al. (2021)[57]	7	Russia	Reconstruction of various bone deformities of the lower extremity using custom implants	Average Harris hip score improved (37.8–80.2) after surgery (improvements in both pain and function); decreased invasiveness due to drilling of screw canals from inside the joint; early weight-bearing achieved in all cases. Early postoperative dislocation of hip joint in 1 case (instability not revealed in follow-up radiographs)
Wang et al. (2020)[58]	1	China	Revision total hip arthroplasty for segmental bone loss of proximal femur and prosthetic stem fracture using custom porous titanium prosthesis	Symptom-free with Harris hip score of 91 at 2-year follow-up, radiographic evidence of osseointegration, and no signs of implant loosening or subsidence; independent ambulation at 6 months postoperatively
Wang et al. (2021)[59]	88	China	Surgical treatment of complex acetabular fractures using PLA 3D-printed pre-contoured plates	Mean operative time and mean blood loss were significantly less with the 3D-printed plates. There was no significant difference in the rates of excellent and good outcome per Matta's radiographic grading between the 3D-printed and conventional techniques. Eleven patients developed DVT in the 3D surgical group versus 16 who developed DVT in the conventional surgery group. One patient in the 3D surgical group developed a deep infection that was treated with debridement and antibiotics.
Wang et al. (2020)[60]	1	China	Treatment of knee inflammation with TKA revision using porous pure tantalum	Over 12 months postoperatively, the patient recovered mobility and reported no remaining discomfort.
Wong et al. (2021)[61]	1	Hong Kong	Resection of low grade pelvic chondrosarcoma and reconstruction using Ti_4Al_6V implant	Histology showed clear resection margin; errors of achieved resection and planned implant position deviated 1–4 mm; patient could walk unaided with good hip function; no tumor recurrence or implant loosening at 11 months postoperatively
Wong et al. (2015)[62]	1	Belgium	Partial acetabular resection for pelvic chondrosarcoma and insertion of 3D-printed patient-specific implant	No neurovascular complications or wound infection; patient was fully weight-bearing 4 weeks after surgery and without a brace at 8 weeks. At 10 weeks, no hip pain and walking independently; no evidence of tumor recurrence
Xu et al. (2016)[63]	1	China	Staged spondylectomy for C2 Ewing sarcoma using titanium alloy implant	Good neurologic function postoperatively, no tumor recurrence at 1-year follow-up, ambulation on postoperative day 7, evidence of implant osseointegration, no subsidence or displacement of the implant Nasogastric tube placement on postoperative day 8 for worsening cough, extubation by day 12

Table 1. Continued

Study	No. of patients	Country	Method	Major finding
Yao et al. (2021)[64]	1	China	Tibiotalocalcaneal arthrodesis for correction of foot drop using Ti_4Al_6V prosthesis	Maximum strain on bone less in P-plate vs. T-plate; AOFAS and 36-Item Short-Form Survey scores were 64 and 75, respectively, at 6 months; gait of patient improved; customized plate well matched to bone surface 3 months postoperatively No major perioperative complications; mechanical weakness of P-plate appeared at the inferior end; bone in contact with the edge of the plate had greater stress than bone at other regions
Zhang et al. (2021)[65]	8	China	Intralesional curettage of giant cell tumor of the proximal tibia and reconstruction using titanium alloy + autograft	Good osseointegration in all patients, no degeneration of the knee joint; no aseptic loosening or breakage of the implant; Musculoskeletal Tumor Rating Scale improved from an average of 12 preoperatively to 28 postoperatively; all patients alive without recurrence or metastasis at end of follow-up No surgery-related complications

Some articles include additional cases unrelated to the specific cases of 3D-printed implants and surgical guides included in this chart.
PLA: poly-lactic acid, VAS: visual analog scale, MSTS: Musculoskeletal Tumor Society, 3D: 3-dimensional, HSS: Hospital for Special Surgery, ROM: range of motion, CT: computed tomography, AOFAS: American Orthopedic Foot and Ankle Society, DVT: deep vein thrombosis, SI: sacroiliac, VEGF: vascular endothelial growth factor, TKA: total knee arthroplasty.

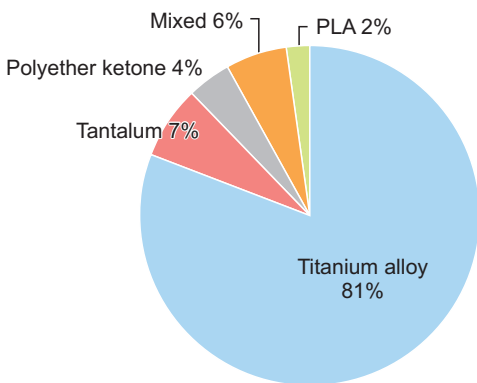

Fig. 1. Materials used in patient-specific implants. Forty-seven of the 58 articles in the literature review involved implants. Titanium alloy includes Ti_6Al_4V and other non-specified titanium alloys, which may be Ti_6Al_4V. PLA: poly-lactic acid.

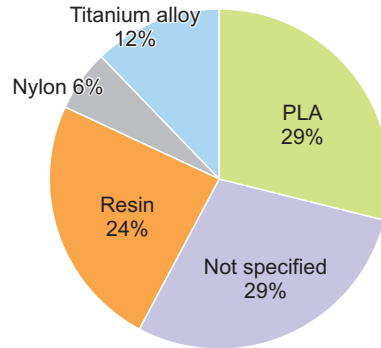

Fig. 2. Distribution of materials used for patient-specific intraoperative guides. Seventeen of the 58 articles in the literature review involved surgical guides. PLA: poly-lactic acid.

materials included resins, polyamides, and nylon powders. Overall, the surgical guides were created using more flexible materials, while implants were made with metals and other rigid materials. Though flexible guides generally functioned well, some cases reported positive margins in bone tumor resection or cutting errors using 3D-printed osteotomy guides. This complication may have been due to the excessive flexibility of the guide material, which may allow the saw to move away from the planned osteotomy line.[20,45]

Biomechanical simulation has proven useful in the design of 3D-printed orthopedic implants. In 1 case, Yao et al.[64] developed a personalized plate for tibiotalocalcaneal arthrodesis and employed finite element analysis to study the biomechanical properties of the model. The study revealed weakness at the inferior aspect of the plate, so its lower width was increased and filleting was used to smooth the edges of the plate. Wong et al.[62] also implemented finite element analysis to quantify stress and strain at various points in the implant, confirming mechanical stability. Importantly, biomechanical stimulation has been used in 1 case to identify flaws in the design of a fractured implant, revealing tiny gas pores, which functioned as crack initiation sites.[47] Not only does simulation aid in the design of these implants, but helps to highlight mistakes, allowing for future alterations and improvement.

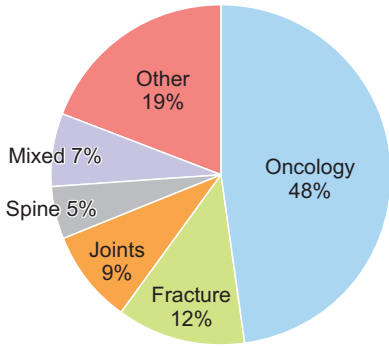

Fig. 3. Distribution of case type. Fifty-eight articles were included.

Three-Dimensional Printing Is Most Commonly Used in Oncology and Fracture Cases

Of the 58 articles included in the literature review (Table 1), oncology was the orthopedic subspecialty that used 3D-printed patient-specific implants most often (48% of articles). Fracture cases (typically complicated fractures) were also fairly common (12%). Fig. 3 shows the distribution of orthopedic subspecialties implementing 3D-printed implants and surgical guides.

Three-Dimensional–Printed Orthopedic Materials Have Produced Favorable Outcomes

Despite the heterogeneous nature of the articles included in this review, there were a few overarching themes in patient outcomes. The majority of studies with 3D printed implants saw improvement in pain and function scores postoperatively compared with preoperatively, and patients experienced functional improvement.[9,12,14,16,27] Radiographs commonly demonstrate evidence of osseointegration and stability.[52,58,63,65] Articles also indicated that custom surgical guides are capable of producing shorter operation times and reduced blood loss.[39,43]

The relative incidence of adverse events is difficult to quantify and often specific to the original diagnosis or surgical technique (Table 1). Many oncology articles reported sequelae of malignancy (local recurrence, distant metastasis, and death).[11,24,31,35,36,56] Local infection (including deep and superficial infections) was also reported in multiple articles.[11,19,27,30,38,50,59] Dislocation of the implant, loosening of implants or screws, and limited activity or range of motion were also reported.[13,14,17,26,30,35,36,50,52,57] For some cases of dislocation, the authors did not specify the material. However, Ti_4Al_6V was used in all other cases of dislocation.[27,30] This may be due to the fact that Ti_4Al_6V is the most common material used; alternatively, this material may be more prone to dislocation. Larger scale studies are needed to evaluate this trend. It is unclear whether the adverse events may have been prevented by implementing traditional implants and/or surgical guides, so additional studies are needed to compare technologies.

DISCUSSION

Three-Dimensional Printing Materials Vary between Implants and Guides

The materials used in each article were evaluated separately for the 3D-printed implants and the 3D-printed guides. For the implants, the majority of the selected articles (81%) use titanium alloys generated via electron beam melting or selective laser melting (Fig. 1). Ti_6Al_4V is well understood, and its inner lattice structure mimics cancellous bone, providing a strong structural basis for osseointegration.[25] Similarly, tantalum is a porous structure that was used in 7% of the implants (Fig. 1). The widespread use of Ti_6Al_4V and tantalum over PLA (2% of articles) and polyether ketone (4% of articles) in implants may be due to the increased porosity of these materials. Natural trabecular bone has a porosity between 70% and 90%,[66] and therefore materials that mimic this porosity will best promote cell survival and stimulate bone formation and osseointegration. Ti_6Al_4V has been shown to have a porosity of up to 81%,[67] tantalum has a porosity of 70%–85%,[68] PLA has a porosity of 86%–90%,[69] and polyether ketone has a porosity of 70%.[70] While all these materials lie within the natural 70%–90% of trabecular bone, PLA and polyether ketone are at the margins of this porosity range, which may account for their less frequent usage. Implants with a lower porosity compared to trabecular bone will be less likely to osseointegrate, and those with a higher porosity are less structurally stable. Importantly, pore size as created using selective laser melting has been shown to be precise across multiple models.[71] This indicates that current technology is able to maintain a consistent pore size across implants, which allows for a controlled study. Since Ti_6Al_4V and tantalum are well understood as compatible implant materials, it is likely that these will be primarily used in the future as the foundation of 3D-printed implants. However, additional characterization of all materials is needed.

In contrast to the implants, the 3D-printed guides most often used PLA (29%) and resin (24%), with 12% of articles using Ti_6Al_4V (Fig. 2). The difference between materials used in implants and guides highlights the importance of biocompatibility for those 3D-printed materials that remain in the patient's body following the procedure. Notably, only 17 of the 58 selected articles discussed a patient-specific guide, whereas 47 of the 58 articles discussed an implant (some articles used both a guide and an im-

plant). The decreased prevalence of 3D-printed implants suggests that patient-specific models may be more useful for situations that require specific biological properties, such as osseointegration and biomechanical stability. In contrast, surgical guides do not have the same strict requirements, as the material does not need to facilitate osseointegration. It is also possible that the need for patient-specific implants is much higher than for guides, as each patient's internal anatomy varies and thus makes a standardized implant less useful. Research interest may also be skewed in favor of implants over guides. Given the benefits offered by implants, we anticipate that future research in this realm will focus on the evaluation of 3D printing for patient-specific implants, rather than surgical guides.

Three-Dimensional Printing May Be Utilized as an Alternative to Standard Orthopedic Implants

The articles selected demonstrate the use of 3D printing in a variety of orthopedic subspecialties, with the most prevalent being oncology (48%) and fracture (12%) (Fig. 3). Overall, the distribution of surgical subspecialties among the selected papers indicates that 3D printing may be most beneficial for pathologies with an irregular anatomy, such as an infiltrative tumor or complex fracture. Relying on commercial implants to fix such anatomically complex lesions may not be adequate; in contrast, 3D printing technology can be used to fabricate implants for patient-specific anatomy.

Overall, the selected papers indicated promising outcomes for the use of 3D-printed implants and guides. Studies reported an improvement in postoperative pain and function scores compared to preoperative scores, with patients also experiencing functional improvement. An important result to highlight is that multiple studies found that patient-specific implants demonstrated radiographic evidence of osseointegration and stability. With regards to intraoperative differences, articles indicated that some custom guides resulted in a shorter operation time and less blood loss. It is notable that there were also common themes of adverse events. For the oncology articles, local recurrence, metastasis, and death were the most common sequelae. Local infection was also a common complication. Regarding the implant itself, dislocation (often with Ti_4Al_6V), loosening of the implant of screws, and limited activity or range of motion were reported. It is important to note that many of the complications are oncological, which may reflect more on the prevalence of oncology articles rather than the abilities of the 3D-printed aides. However, if 3D printing is more likely to be used in oncology, then this is an important consideration. Overall, it is necessary to rigorously interrogate both the benefits and drawbacks of using this new technology in any subspecialty.

Moving forward, it will be critical to consider the potential advantages of the 3D-printed implants and guides in comparison to their standardized counterparts. Only 5 of the 58 selected articles reported N > 20, as most of the studies were small-scale case reports. All studies focused on 3D-printed surgical aides, and none of the studies compared outcomes to conventional implants and guides using a control group. To assess the utility of 3D-printed surgical aides, it is necessary to compare them to the conventionally available alternatives. It is understandably challenging to do so as the personalized nature of 3D printing makes it difficult to match patients; however, this is a necessary analysis. Some of the selected articles reported similar outcome measures, but overall these measures varied among articles, making it difficult to compare outcomes. As the technology of 3D-printed implants evolves and becomes more prevalent, it is important to consider how we will continue to evaluate the efficacy of this technology, especially in comparison to conventional strategies

Food and Drug Administration Regulations May Account for the Limited Use of 3D-Printed Materials in the United States

Despite the demonstrated potential for 3D printing in orthopedic surgery, patient-specific 3D-printed implants are sparsely implemented, especially in the United States. The Food and Drug Administration (FDA) requirements for 3D-printed medical devices fall under the same requirements as traditional manufacturing, distribution, and sale of medical devices.[72] Most patient-specific 3D-printed implants fall under the category of a 510 (k), which allows an expedited approval process for medical devices that are "substantially equivalent to one legally in commercial distribution."[72] However, the manufacturing processes would need to be validated per the Quality System Regulation (21 CFR 820) to ensure the requirements of the device are continually being met.[73]

The relatively low implementation of patient-specific implants (compared with commercially available implants) in the United States may be due in part to these regulations. In addition, the 3D printing process itself needs to be validated per the FDA Quality System Regulation (21 CFR 820) to ensure the requirements of the product are continually being met.[73] This additional point of regulation is one downside of 3D printing patient-specific implants, necessitating larger studies to determine whether the benefits outweigh the drawbacks. The am-

biguity surrounding regulations may also restrict institutions from using 3D-printed implants and surgical guides. Furthermore, the requirement and timeline of authorization constitute another hurdle that may deter a hospital or a physician from using 3D-printed devices. The process of obtaining approval for the use of a 3D-printed implant or guide therefore may be a barrier to the expanded use of this technology.

Future Studies Are Needed to Evaluate and Compare 3D-Printed Orthopedic Implants

This review of the literature revealed a number of case reports, case series, and small prospective and retrospective studies involving the use of intraoperative 3D-printed implants and/or surgical guides. The literature lacks randomized controlled trials that evaluate the benefits of 3D-printed orthopedic implants as compared with the standard of care (commercially manufactured implants). Studies could also evaluate different materials and manufacturing processes for the same surgical indication to determine optimal protocols. Furthermore, longitudinal studies are needed to evaluate patient-specific orthopedic implants over longer periods of time, as case reports only include data up to the last follow-up, which is rarely more than a few years. Finally, a rigorous demonstration of the benefits of 3D-printed implants may alleviate some of the legal and regulatory ambiguity that is currently present by allowing the development of clear guidelines, which may also increase the safety and accessibility of this technology.

The authors also recognize the limitations of this review of the literature. A lack of standardized outcome measures among the selected articles makes it challenging to compare and summarize the studies; this speaks to flaws in the current published research. In addition, the review includes studies from multiple countries that may have different regulations surrounding the use of 3D printing technology in orthopedic surgery.

CONCLUSIONS

This review of the literature presents recent applications of 3D-printed patient-specific implants in the field of orthopedic surgery. Three-dimensional printing has potential as an alternative to commercially available implants, as it allows for increased customizability in cases of anatomic complexity and variation. A variety of printing materials and methods are being used across a range of orthopedic subspecialties. There is a need for large controlled studies to compare patient-specific orthopedic implants with the standard of care, evaluate their safety, and provide a basis for the regulation of these devices.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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